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08/031,562	03/16/93	BOGOCH	S

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EXAMINER	
KRSEK STAPLES, J	
ART UNIT	PAPER NUMBER
1813	14

DATE MAILED: 02/22/95

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☑ THE PERIOD FOR RESPONSE:

a) ☑ is extended to run 4 months or continues to run _____ from the date of the final rejection

b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition , and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☑ Applicant's response to the final rejection, filed 12-13-94 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☐ The proposed amendments to the claim and /or specification will not be entered and the final rejection stands because:

   a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.

   b. ☐ They raise new issues that would require further consideration and/or search. (See Note).

   c. ☐ They raise the issue of new matter. (See Note).

   d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

   e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

   NOTE: _____

2. ☐ Newly proposed or amended claims _____ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☑ Upon the filing an appeal, ~~the proposed amendment~~ ☐ ~~will be entered~~ ☐ ~~will not be entered~~ and the status of the claims will be as follows:

   Claims allowed: _____
   Claims objected to: _____
   Claims rejected: 1-2

   However;

   ☑ Applicant's response has overcome the following rejection(s): Rej of claims 1+2 under 35 U.S.C 103. Upon reconsideration, the rejection of claims 1+2 under 35 USC 101 has w/s bee. withd.

4. ☑ The ~~affidavit, exhibit or~~ request for reconsideration has been considered but does not overcome the rejection because See attached

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficent reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☐ Other

Applicant states that it is very relevant that actual survival in human cancer patients, which is the end-measure of all other factors in cancer treatment, is quantitatively related to the concentration of anti-Recognin antibody. Applicant argues that one of the factors in using tumor associated antigens (TAAs) taught by Stevenson is the formation of antibodies which can lead to autoimmune reactions. Applicant states that this is not a problem with Recognin because the Recognins are not constituents of normal cells and therefore normal cells are not at risk in either active of passive treatment with Recognins or anti-Recognins. Applicant also states that Recognins have a natural immunity mechanism because anti-Recognins increase with age in normal healthy individuals as the risk for cancer increases and that anti-Recognins increase with age more strikingly and start earlier in healthy members of cancer high-risk families. Applicants state that Recognins satisfy the criteria set forth for cancer vaccines by the Bystryn reference in that 1.) Anti-Recognins are powerful cytotoxic agents against cancer cells and Recognins are able to induce a clinically effective immune response in humans and 2.) Recognins are expressed on the tumor to be treated where it can be seen by an interact with immune effector mechanisms. Applicant argues that because Recognins satisfy these requirements they meet the criteria for the definition of cancer vaccines.

Applicant's arguments have been considered but are not deemed to be persuasive. Applicant states that Recognin satisfies the first criteria set forth by Bystryn for a tumor vaccine which is the ability to induce clinically effective immune responses in human. Following this criteria Applicant states that the anti-Recognins are powerful static and cytotoxic agents against cancer cells because they interact with Recognin. However, as stated in the previous Office

action, the cytotoxicity of the anti-Recognin antibody to cancer cells *in vitro* is not sufficient to demonstrate that the administration of the Recognin would result in the treatment of cancer because the cytotoxicity measured *in vitro* cannot be extrapolated to the treatment of tumors *in vivo* where other factors such as the anatomical location of the tumor, the tumor mass, and the long tumor-host relationship make the *in vivo* system much more complex and unpredictable. Applicant has stated that it is very relevant that actual survival in human cancer patients, which is the end-measure of all other factors in cancer treatment, is quantitatively related to the concentration of anti-Recognin antibody. However, it is maintained that the specification does not teach that Recognin, when administered as a vaccine, prevents or treats clinical cancer. The correlation of naturally occurring anti-Recognin antibodies in cancer patients with survival and the *in vitro* cytotoxic activity of anti-Recognin is not sufficient to predict whether the administration of Recognin will result in the treatment of clinical cancer because it has not been determined whether anti-Recognin antibodies generated by the administration of Recognin are capable of preventing or inhibiting tumor growth *in vivo* or whether antibody levels sufficient to treat clinical cancer are generated by the administration of Recognin.

JKS

Julie Krsek-Staples, Ph.D.
February 14, 1995

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